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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/192,579	11/17/1998	FRANCO MENOZZI	960-34	9973

7590 04/30/2004

NIXON AND VANDEHYDE
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 ARLINGTON, VA 22201

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/192,579

Applicant(s)

MENOZZI ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14April2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): none, see attached Detailed Action.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: 68-70.Claim(s) rejected: 56-67.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

DETAILED ACTION

1. Applicants' Second Response to Final Office Action, received 14 April 2004, is acknowledged. Claim 66 has been amended.
2. Applicants have presented new claims 82-84 without canceling a corresponding number of finally rejected claims. Therefore, the proposed amendments will not be entered.
3. Claims 56-70 are pending and under consideration.

Rejections Maintained

4. The rejection of claims 56-67 under 35 U.S.C. 102(b) as being anticipated by Menozzi et al (*Abstracts of the General Meeting of the ASM*, 95(0):193, abstract B-159) is maintained for the reasons put forth in prior Office Actions.

Applicants argue that to be anticipatory, a reference must disclose each and every element of the claim in the same order as arranged in the claim. Menozzi et al does not disclose the amino acid sequences, antigens, nor monoclonal antibodies of the instant claims and that Menozzi et al fail to disclose any procedure concerning the cloning of the gene coding for HBHA and what microorganisms can be used to express it. A declaration by Dr. Menozzi is provided to support applicants' argument that the reference is not enabled.

The examiner has considered applicants arguments, but does not find them persuasive. The instant claims are drawn to a product, HBHA, and not to a method of making. As stated in previous rejection explanations, in the absence of evidence to the contrary, Menozzi et al do teach the claimed proteinic mycobacterial antigen based upon the data that: 1) the instant inventors and their laboratories are also authors on the cited reference, 2) both proteins have the identical name, 3) both proteins are from identical mycobacterial sources, and 4) both proteins have identical characteristics. The amino sequence of the cited reference

Art Unit: 1645

HBHA and its binding to specific monoclonal antibodies would be identical to the HBHA of the instant claims. Applicants' arguments concerning enablement have not been found persuasive because given the bacterial source, cell wall origin, molecular weight, specific binding activities, specific inhibition characteristics, one of ordinary skill in the art has been provided sufficient guidance to produce the claimed product. In addition, applicants' argument has not put forth data indicating the contrary, i.e., the HBHA of the cited reference **is not** the claimed HBHA. Therefore, the rejection is maintained for reasons of record.

5. The objection to claims 68-70 as being dependent from rejected claim is maintained for reasons of record.

Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

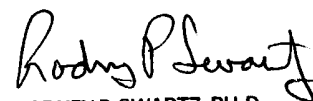
Application/Control Number: 09/192,579

Page 4

Art Unit: 1645

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Rodney P. Swartz". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

RODNEY P. SWARTZ, PH.D

PRIMARY EXAMINER

Art Unit 1645

April 28, 2004